REMARKS

Status of the Claims

Claims 1-19 and 21-27 are currently pending.

Claims 1-19 and 21-27 are currently rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,707,962 to Chen, *et al.* (hereinafter the "Chen" reference), in view of U.S. Patent No. 4,496,468 to House, *et al.* (hereinafter the "House" reference), in further view of U.S. Publication No. 2001/0018614 to Bianchi (hereinafter the "Bianchi" reference), in further view of U.S. Patent No. 5,405,390 to O'Leary, *et al.* (hereinafter the "O'Leary" reference), and in further view of U.S. Patent No. 6,679,918 to Benedict, *et al.* (hereinafter the "Benedict" reference). For the reasons stated below, the Applicants respectfully traverse the pending rejection and request that the pending rejection be withdrawn.

35 U.S.C. §103(a)

In making an obviousness rejection, "[t]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." MPEP §2142. In order to fulfill this obligation:

[T]hree basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

MPEP §2142 (emphasis added); See also MPEP §2143.

The Applicants respectfully submit the a *prima facie* case of obviousness has not been made with respect to the pending rejection of claims 1-19 and 21-27 because the February 7, 2007 Office Action does not show that the cited references "teach or suggest all the claim limitations." The pending Office Action does not specifically address all of the claim limitations for any of the pending claims, nor does the pending Office Action set forth where in the cited references each claim limitation is alleged to be found. The pending Office Action therefore does not set forth a *prima facie* showing that the cited references teach or suggest all of the claim limitations with respect to any of the currently rejected claims. See, e.g., MPEP §2143.03 ("To

establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. <u>In re Royka</u>, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). 'All words in a claim must be considered in judging the patentability of that claim against the prior art.' <u>In re Wilson</u>, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).")

Furthermore, the February 7, 2007 Office Action improperly relies upon non-analogous art as a basis for the pending obviousness rejection. The MPEP states, "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." MPEP §2141.01(a) (quoting <u>In re Oetiker</u>, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992)); see also MPEP §2145.

In particular, independent claims 1, 12 and 19 each recite "an exothermic salt that heats upon contact with a reconstitution fluid." The pending Office Action admits that the Chen reference "does not teach adding an exothermic salt to the mixture," February 7, 2007 Office Action at p. 3, but then relies upon the House reference in asserting that "it would have been obvious at the time the invention was made to add an exothermic salt to the solution to add heat in order to enhance the mixing of the components." February 7, 2007 Office Action at p. 3. The Applicants respectfully disagree and submit that it would not have been obvious to one of ordinary skill in the art to modify and combine the Chen and House references as suggested by the Examiner because the House reference is non-analogous.

A. Field of Applicant's Endeavor

The House reference is not "in the field of applicant's endeavor." See MPEP §2141.01(a). The present application relates to "a novel system for reconstituting bone paste, and/or other biomedical pastes or powders, that results in decreasing the time involved in processing such pastes, as well as diminishing the costs and inefficiencies associated with their storage." Specification p. 2 lines 4-7 (emphasis added). In contrast, the House reference relates to "aqueous well servicing fluids" for use in the oil and gas industry, and more specifically to "polymeric compositions useful for thickening aqueous mediums, especially heavy brines having a density greater than about 13.5 pounds per gallon." See, e.g., House at Col. 1 lines 6-7, and Col. 1 line 58 to Col. 2 line 23 (emphasis added). The oil field applications of heavy brine solutions as addressed by the House reference are within an entirely different industry that the

biomedical pastes and powders addressed in the present application, and certainly are not within the same field of endeavor. See In re Clay, 966 F.2d 656, 659, 23 U.S.P.Q. 2d 1058, 1060 (Fed. Cir. 1992) (Finding that the cited reference could 'not be considered to be within Clay's field of endeavor' even though both related to the same industry.)

B. The Particular Problem With Which the Inventor was Concerned

The House reference is not "reasonably pertinent to the particular problem with which the inventor was concerned." See MPEP §2141.01(a). The Federal Circuit has explained that:

A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. Thus, the <u>purposes of both the invention and the prior art are important</u> in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve. If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it.

In re Clay, 966 F.2d at 659, 23 U.S.P.Q. 2d 1061 (Finding that the problem of recovering oil from rock was not reasonably pertinent to the problem of preventing loss of stored product to tank dead volume while preventing contamination of such product) (emphasis added).

The February 7, 2007 Office Action asserts that "House teaches that it is known in the art to add exothermic salts to aid in liquefying a gelatinous material." February 7, 2007 Office Action at p. 3. As an initial matter, this assertion, is incorrect. The House reference does not teach that it is known in the art to add exothermic salts to aid in liquefying a gelatinous material. First, as discussed above, the House reference is not "in the art" with respect to the present application. Second, the House reference discloses that:

The water and inorganic salt are preferably added separately, the water being added first followed by addition of the inorganic salt. In this manner the exothermic heat of solution of the salt raises the temperature of the HEC composition, preferably to a temperature greater than about 150 °F. If the water and inorganic salt are not added separately, then it is desirable to heat the HEC composition to a temperature of at least 150 °F in order to best activate the HEC for use in heavy brines.

House at Col. 4 lines 26-31. The House reference thus teaches the use of an exothermic salt to achieve activation of the HEC, and the HEC is the "primary component to effect thickening of aqueous liquids." House at Col. 2 lines 29-30 (emphasis added). The House reference thus discloses the use of an exothermic salt to facilitate the thickening of an aqueous liquid, which is in direct contradiction to the liquification of a gelatinous material. Given this contradictory purpose for use of an exothermic salt, as well as given the vastly different purposes of the presently claimed compositions and the HEC compositions for use in oil fields described by the House reference, one having ordinary skill in the art of the present application would not have been motivated to consider the House reference in making the present invention.

Additionally, there are significant differences in structure and function between the presently claimed compositions and the compositions disclosed in the House reference. For example, independent claim 1 of the present application recites a "composition comprising freeze-dried demineralized bone matrix DBM particles, an exothermic salt that heats upon contact with a reconstitution fluid, and a carrier, wherein said carrier is gelatin, hyaluronic acid, polyethylene oxide, polyvinylpyrrolidone, polyvinyl alcohol, collagen or dextran, or a combination thereof." The House reference, in contrast, describes "an HEC composition for use in viscosifying aqueous liquids comprising HEC, an oleaginous liquid, water, an inorganic salt which has an exothermic heat of solution, and a compatiblizing agent." House at Col. 2 lines 5-8. The compositional components aside from the exothermic salt are thus significantly different. Further, as described above, the function of the House compositions is to thicken aqueous mediums such as the heavy brine solutions used as well servicing fluids in oil fields, which differs greatly from functions of the presently claimed compositions.

In view of the forgoing discussion, the Applicants respectfully submit that it would not have been obvious to one having ordinary skill in the art to combine the Chen reference and the House reference in the manner suggested in the February 7, 2007 Office Action. The Applicants therefore respectfully request that the pending rejection of claims 1-19 and 21-27 under 35 U.S.C. §103(a) be withdrawn.

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CONCLUSION

In view of the Arguments presented above, the Applicants respectfully submit that claims

1-19 and 21-27 are in a condition for allowance, and respectfully request that these claims be

allowed.

Applicants believe that no fee is currently due with the present submission. However, the

Commissioner is hereby authorized to charge any fees that may be necessary, or credit any

overpayment, to the Deposit Account of McAndrews, Held & Malloy, Account No. 13-0017.

Respectfully submitted,

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